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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,505	07/22/2003	Jane Ye	CL001158DIV2	1679

25748 7590 07/27/2005

CELERA GENOMICS
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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,505	YE ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0.0

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-5, 8-9, 10-11, and 22-23, drawn to nucleic acids encoding SEQ ID NO: 2, vectors and host cells comprising the nucleic acid, and a method of making a polypeptide, classified in class 514, subclass 44.

II. Claims 1-2, 14-15, and 20-21, drawn to polypeptides of SEQ ID NO: 2 and a method to identify an agent that modifies the activity of the polypeptide, classified in class 530, subclass 183.

III. Claims 3 and 12, drawn to antibodies to polypeptides of SEQ ID NO: 2 and a method to identify the presence of the polypeptide in a sample, classified in class 424, subclass 130.1.

IV. Claim 7, drawn to a non-human transgenic animal comprising a nucleic acid encoding SEQ ID NO: 2, or a variant or fragment thereof, classified in class 800, subclass 8.

V. Claim 16, drawn to a method to identify an agent that binds to a peptide of SEQ ID NO: 2, a composition comprising the agent identified and a method to treat a disease or condition with the agent, classified in class 424, subclass 78.1.

VI. Claim 19, drawn to a method to identify a modulator of expression of a peptide of SEQ ID NO: 2, classified in class 536, subclass 24.5.

VII. Claims 6 and 13, drawn to a gene chip comprising a polynucleotide encoding a peptide of SEQ ID NO: 2 and a method to detect the presence of a polynucleotide encoding SEQ ID NO: 2 in a sample, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Group II is related to Group I as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of Group II may be made from cells not transformed, or by chemical synthesis, and the transformed cells may be used for *ex vivo* gene therapy or identifying agents that increase expression of proteins.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the polypeptides of Group II has separate utility in identifying a modulators of the activity of the polypeptide, and the antibody may be used to identify individuals that require modified treatment modalities (SPECIFICATION, p. 27, paragraph 4). See MPEP § 806.05(d).

The invention of Group IV is patentably distinct from the inventions of Groups I-III. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and they have different structural considerations, which yield

different functions and effects, which require different, non-coextensive search and examination considerations. To wit, the nucleic acid of Group I may be used to make protein or treat disease, the proteins of group II require a consideration of the structure and functions which may be modulated, the antibodies of Group III require a consideration of the structure and functions of the antibody which are required to determine modified treatment modalities, and the transgenic animal of Group IV may be used to study disease, which requires a consideration of the phenotype and its relevance to disease.

Groups V-VII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and require different steps, requiring different, non-coextensive structural considerations. To wit, Group V requires a consideration of the structure required for the binding assays and the applicability of a so-found agent to treatment of a disorder or disease. Group VI requires a consideration of the structure required to identify a modulator of expression, as well as the structure of the nucleic acid which such function may act through. Group VIII requires a consideration of the structure of the structure of the polynucleotide and how it determines the presence of another nucleic acid, as well as the structure of a gene chip. Such distinct, non-coextensive structural considerations are what gives rise to the distinct functions and effects of each invention.

Groups I-III are related to groups VI-VII as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each product has been incorporated with a particular process of use, and therefore the separate processes of use inherently indicate that the product may be used in a different process. Moreover, the structural considerations, as evidenced in the prior paragraphs, demonstrate the distinctness of each group of invention.

Group IV is patentably distinct from Groups V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and have different structural considerations, yielding different functions and effects. To wit, as shown above, the transgenic animal may be used as a model of disease, while the methods may be used identify agents for modulating expression of protein or treating disease. These distinct non-coextensive considerations are what yield the distinct functions and effects of the inventions.

Moreover, each invention, due its specific non-coextensive structure, requires distinct non-coextensive search and examination considerations, which would pose a serious burden on the examiner. Furthermore, such burden is not diminished by the fact that certain groups are broadly classified in the same classification, as these classes include all proteins used in bioaffecting processes (i.e., class 424), and therefore the search within that class would be non-coextensive and still place a serious burden on the Examiner to search and examine any two groups together.

Because these inventions are distinct for the reasons given above and the search and examination required for any particular group is not required of any other group, restriction for examination purposes as indicated is proper.

In the event that Applicant should choose one of the inventions of Groups I, II, or III, and the particular is found otherwise allowable, Applicant will be allowed rejoinder of those inventions of Groups V, VI, or VII, commensurate in scope with the otherwise allowable composition, under In re Ochiai. E.g., if Applicant elects the polypeptide, those inventions of V, VI or VII that utilize the polypeptide in the methods steps will be rejoined with the polypeptide group of invention; those that require the nucleic acid will be considered with the nucleic acid, and those that require the use of the antibody will be rejoined with the antibody. (See Below)

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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